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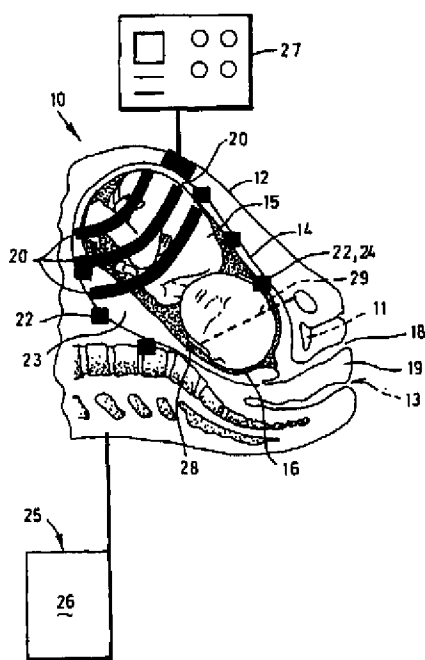
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(54) Title: OBSTETRICS TRAINING AID



(57) Abstract: An obstetrics training aid (10) comprises a housing (12) to simulate the lower abdomen of a female human. A flexible sac or chamber (14) within the housing (12) simulates a uterus and contains a liquid (28) to simulate amniotic fluid. A fetus-simulating body (15), which is located within the flexible chamber (14), is hollow at least within the head-simulating end part (16) and contains liquid dyed with a selected one of a plurality of coloured dyes, e.g. to simulate blood (as can arise in post-partum haemorrhage) and/or to simulate bowel contents (as can arise in foetal distress). The flexible chamber (14) also contains a bag (23) attached to body (15) and simulating a placenta and/or contains replaceable simulations of amniotic membranes to allow the training aid (10) to be used to simulate premature and artificial rupture of such membranes in real life. The housing (12) has a lower opening (18) that is provided with a flexible boundary and is to simulate a cervix. This cervix-simulating opening (18) may be covered by a removable replaceable membrane (19), simulating a perineum and upon which an episiotomy procedure may be practised by a trainee user of the aid (10). A plurality of tubular elements (20) encompass and engage the upper end of flexible chamber (14) around the upper end of fetus-simulating body (15), and valve means are provided for introducing fluid, e.g. air or water, under pressure from a cyclically variable supply - to simulate maternal contractions - into the tubular elements (20) such that they can effect a squeezing action on the rear end of the fetus-simulating body (15) and, due to the latter's curved shape, cause it to move in a direction outwardly of the cervix-simulating opening (18). A plurality of electromagnets (22) located at predetermined positions within the housing (12) co-operate selectively with one or more elements (24) susceptible to magnetisation that are attached to the fetus-simulating body (15) to effect

positional changes of the foetal-simulating body (15) within the flexible chamber (14) and/or the housing (12) thereby to simulate a variety of positions and/or presentations of the foetus-simulating body (15) within the simulated uterus (14).

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## OBSTETRICS TRAINING AID

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**DESCRIPTION****Technical Field**

10 This invention relates to training aids, and particularly such aids for training medical personnel in aspects of obstetrics. Optionally embodiments of the invention may additionally aid in training such personnel in aspects of gynaecology.

15 Medical personnel such as obstetricians, non-obstetrician doctors, midwives and students for these occupations, require training in the accurate determination of obstetric conditions, especially during childbirth by a female patient. In the past the primary, if not only, method available for acquiring the skill of such accurate determination has been experience gained from live physical examination of many women during the process of delivering a child. However such live physical examination by a trainee is a non-essential intervention that can be disturbing to the  
20 mother-to-be, and may be medically detrimental to the mother-to-be and/or to the baby being delivered.

Clearly it is desirable to provide a training aid whereby the above-mentioned and/or other disadvantages of obstetrics training can be overcome or at least minimised.

25

**Summary of the Invention**

According to the present invention there is provided an obstetrics training aid comprising:

- 30 a housing,
- a flexible chamber within the housing to simulate a uterus,

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a foetus-simulating body within the flexible chamber;  
the housing having an opening provided with a flexible boundary to simulate a cervix,  
and motion imparting means for moving the foetus-simulating body within the chamber  
in a direction outwardly of the cervix-simulating opening to simulate a birthing  
5 process, i.e. egress of a real foetus from the cervix.

Preferably the motion imparting comprise tubular elements engaging the flexible  
chamber, and fluid supply means for introducing fluid under pressure into said tubular  
elements.

10 In use, the tubular elements can be filled sequentially with water or air under pressure  
to effect a squeezing action on the foetus- simulating body, and, due to the latter's  
curved shape, result in its movement in a direction outwardly of the cervix-simulating  
opening.

15 In one preferred arrangement, the fluid supply to the tubular elements is varied  
cyclically, e.g. via a foot-operated pump, to simulate maternal contractions.

Preferably the obstetrics training aid comprises:

20 electromagnets within the housing;  
elements of magnetic material attached to the foetus-simulating body to be  
magnetically coupled to the electromagnets; and  
control means operable on the electromagnets to effect, via said elements of  
magnetic material, variations in position of the foetus-simulating body within the  
25 flexible chamber and/or the housing. Operation of the control means can thus simulate  
a variety of positions and/or presentations of the foetus-simulating body.

The cervix-simulating opening may be covered by a removable replaceable membrane  
(simulating a perineum) upon which an episiotomy procedure may be practised by a  
30 trainee user of the obstetrics training-aid.

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The flexible chamber may contain a liquid to simulate amniotic fluid. The liquid may be dyed with a selected one of a plurality of coloured dyes, e.g. to simulate blood (as can arise in post-partum haemorrhage) and/or to simulate bowel contents (as can arise in foetal distress).

5

The flexible chamber may contain a bag attached to said body and simulating a placenta.

10

Advantageously the body is hollow — at least within a head-simulating portion thereof — and said portion contains fluid.

15

Preferably the housing and chamber are operable to permit removal of the foetus-simulating body and its replacement by another such body of different size and/or weight.

#### Brief Description of the Drawings

20

By way of example one embodiment of this invention will now be described with reference to the accompanying drawings of which is a schematic cross-sectional diagram of apparatus constituting a training aid according to the invention.

#### Detailed Description of Example(s) of the Invention

25

The illustrated obstetrics training aid 10 comprises a housing 12 to simulate the lower abdomen of a female human, the housing 12 containing a flexible sac or chamber 14 to simulate a uterus. A body 15, shaped to simulate a foetus, is located within the flexible chamber 14, and this foetus-simulating body is hollow at least within the head-simulating end part 16. The housing 12 has a lower opening 18 that is provided with a flexible boundary and is to simulate a cervix.

30

A plurality of tubular elements 20 encompass and engage the upper end of flexible chamber 14 around the upper end of foetus-simulating body 15, and valve means (not

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shown) are provided for introducing fluid, e.g. air or water, under pressure into the tubular elements 20 such that they can effect a squeezing action on the rear end of the fetus-simulating body 15 and, due to the latter's curved shape, cause it to move in a direction outwardly of the cervix-simulating opening 18. The fluid supply to the tubular elements 20 may be varied cyclically, e.g. via a foot-operated pump, to simulate maternal contractions.

A plurality of electromagnets 22 are located at predetermined positions within the housing, and a corresponding number of elements 24 of magnetic material are attached to the fetus-simulating body 15 such as to be magnetically coupled to the electromagnets 22. Control means 25 for the training aid comprises a computer 26 programmed to provide electrical output signals to the electromagnets 22, effects (via the elements 24 of magnetic material) variations in position of the foetal-simulating body 15 within the flexible chamber 15 and/or the housing 12. Programmed operation of the control means 25 can thus simulate a variety of positions and/or presentations of the fetus-simulating body 15 within the simulated uterus 14. The training aid 10 also comprises a simulated cardiotocogram (CGT) apparatus connected appropriately to the housing 12 and to the computer 26. The simulated CGT apparatus includes a display unit 27 that in use provides a display of information corresponding to that provided by a real CGT display in a plurality of scenarios of real situations as simulated by the program active on the computer 26.

The cervix-simulating opening 18 may be covered by a removable replaceable membrane 19, simulating a perineum and upon which an episiotomy procedure may be practised by a trainee user of the obstetrics training-aid 10.

The flexible chamber 14 may contain a liquid 28 to simulate amniotic fluid. The liquid may be dyed with a selected one of a plurality of coloured dyes, e.g. to simulate blood (as can arise in post-partum haemorrhage) and/or to simulate bowel contents (as can arise in foetal distress). The flexible chamber 14 may also contain a bag 23 attached

- 5 -

to said body 15 and simulating a placenta; and/or may contain replaceable simulations of amniotic membranes to allow the training aid 10 to be used to simulate premature and artificial rupture of such membranes in real life.

5 The hollow head-simulating part 16 of the foetus-simulating body 15 contains fluid, e.g. water, and it is considered that (with a flexible wall to this head portion) different head sizes can be represented by altering the pressure of the fluid within head-simulating part 16. In addition, by measuring this pressure, an accurate feed-back signal can be derived indicative of the forces exerted by the simulated contractions  
10 (effected by tubular elements 20) and/or by instruments (e.g. forceps) employed by the trainee. This head-simulating head portion 16 may be formed on its exterior surface with representations of fontanelles, and/or suture lines and/or other moulding features of a real foetal skull.

15 Preferably the housing 12 and chamber 14 are provided with upper or side openings or otherwise operable to permit removal of the foetus-simulating body 15 and its replacement by another such body of different size and/or weight.

20 The outer housing 12 may be shaped to correspond to parts of the female body, and may include a simulated human arm for use in training a student in techniques of taking a patient's pulse, blood pressure and temperature (under the armpit). The aid 10 may also include a loudspeaker and/or microphone for use in transmitting verbal messages or information (e.g. of certain previous and/or extant medical conditions) between the trainee and a supervisor or examiner located at a remote location.

25 It is envisaged that, by suitable programming of computer 26, the training aid 10 can be used as a birthing simulator that is capable of reproducing most if not all obstetric scenarios and simulate full responsiveness to management of a patient, i.e. with drugs or procedures. It is envisaged that use of the simulator 10 can increase the speed and  
30 quality of learning as well as allowing objective assessment of physical examinations,

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and the management of various clinical situations and protocols. In this way the training aid 10 can be an adjunct to teaching and precede (but not replace) the examination of consenting patients. It is also envisaged that this training aid 10 could assist in setting a minimum standard of training proficiency that would have to be attained before staff are allowed to practice on a hospital labour ward.

It is considered that the training aid 10 can be used for training and examining students of obstetrics in matters appertaining to all three labour stages, including the actual birth process.

10

#### **THE FIRST STAGE OF LABOUR**

This is the time from the onset of regular contractions, until the cervix is fully dilated.

Using aid 10, the student will be able to practise the following: -

- Vaginal examination to assess:
  - 15                      Cervical dilation
  - Cervical length
  - Cervical consistency
  - Position and station (position of the head in relation to the pelvis)
  - Presenting part of the foetus
  - 20                      Degree of moulding (the amount of overlapping of the foetal skull bones)
  - State of liquor – clear or sticky and dark green (signifying evacuation of fresh bowel contents - a sign of foetal distress).
- Interpretation of the simulated cardiotocogram (CTG)–device 27 used in real
  - 25                      life to assess the foetal heart rate and maternal uterine contractions, and give an indication of foetal distress.
- Interpretation of maternal urine analysis for the presence of protein or glucose.
- Monitoring of vital signs including pulse, blood pressure, temperature.
- Interpretation of simulated blood sample analysis
- 30                      - Interpretation of simulated foetal scalp blood sampling (to confirm hypoxia)

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- Induction and augmentation of labour
- Assessment of failure to progress in labour.
- Ineffective contractions.

#### **THE SECOND STAGE OF LABOUR**

- 5 This is from full dilation of the cervix until the foetus is born. Using training aid 10, the student will be able to practise Normal delivery, delivery assisted (with the use of instruments) and complicated deliveries associated with mal-positioning and mal-presentation of the foetus, and Episiotomy

#### **THE THIRD STAGE OF LABOUR**

- 10 This is from the delivery of the baby until the placenta and membranes are delivered. Again, using the training aid 10, the student will be able to practise Delivery of a normal placenta, Post-partum haemorrhage treatment, and Episiotomy repair.

- 15 It is envisaged that, in addition to normal labour stages 1 - 3, the above described and illustrated training aid 10 may be utilised to simulate one or more of *inter alia* the following conditions:

- Pre-eclampsia
- Eclampsia
- 20 Maternal diabetes
- Maternal infection and septicaemia
- Maternal hypertension
- Maternal Epilepsy
- Ante-partum haemorrhage and obstetric shock
- 25 Prolonged pregnancy (exceeding 42 weeks)
- Intrauterine growth retarded foetuses
- Pre-labour rupture of membranes
- Pre-term labour
- Prolapsed cord
- 30 Placental abruption.



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In all the above situations the appropriate vital signs, CTG readings/display, blood and urine (if relevant), will be simulated by the computer 26.

5 It will be appreciated that the above-described and illustrated training aid 10 can be used to provide an all round training in most, if not all, aspects of labour and delivery without having to resort to the patient as a "guinea-pig".

Some of these scenarios will be described in more detail, below:

## 10 **I. EXAMINATION OF ABDOMEN IN PREGNANCY**

Training aid 10 can be used to simulate pregnancies at various gestational ages. The student will be able to palpate the foetus and determine:

The lie of the foetus (vertical, transverse or oblique)

The presenting part (head or buttocks)

15 The engagement of the foetal head i.e. how far the head has descended into the pelvis.

Measure the symphysis-fundal height (measurement from the maternal pubic bone to the top of the pregnant uterus), which gives a rough estimate of how well the foetus is growing.

20 Assess whether there is normal, increased (polyhydramnios) or decreased (oligohydramnios) of amniotic fluid, these scenarios being simulated by altering the amount of amniotic fluid pumped in the uterine cavity simulated by chamber 14,

Listen to the foetal heart sounds simulated by a loudspeaker within the chamber 14.

25

## **II. PRE-TERM LABOUR**

This occurs when a woman goes into labour before 37 completed weeks of pregnancy, and it is desirable that students learn the causes of pre-term labour and recognise that the mother may have one (or more) of the following conditions, which training aid 10

- 9 -

can simulate, that pre-dispose a patient to pre-term labour, namely: pre-eclampsia, ante-partum haemorrhage, and polyhydramnios.

5 Training aid 10 can also simulate circumstances where the cervix begins to dilate and there is leakage of amniotic fluid.

These scenarios enable the student to consider whether the foetus is likely to survive at that particular gestational age, and to decide whether the delivery should proceed or be stopped with tocolytic drugs. Tocolytic drugs inhibit smooth muscle contractility.

10 Administration of the drug, at the correct dosage, will produce the appropriate response in our model. If too much is given then the following side effects can be simulated increased maternal heart rate and pulmonary oedema (the mother can complain of acute shortness of breath).

### 15 **III. PRE-TERM PREMATURE RUPTURE OF MEMBRANES (PPROM)**

This occurs when the amniotic membranes rupture before 37 weeks gestation, without active uterine contractions. Using the training aid 10, the student can perform, in a simulation, a sterile vaginal speculum examination to confirm rupture of membranes. Leakage of fluid causes an increase in vaginal pH, which may be measured using a

20 Nitrazine swab. From such examination and analysis, the student can estimate gestational age of the foetus, it's ability to survive at that age, and maternal risks, so as to decide whether to induce labour.

### **IV. INDUCTION OF LABOUR**

25 The training aid 10 may be used to assess any one of the following circumstances:

- pregnancy-induced hypertension (pre-eclampsia)
- prolonged pregnancy (beyond 42 weeks gestation)
- intrauterine growth retardation
- ante-partum haemorrhage
- 30 diabetes mellitus (in a known diabetic mother or one with gestational diabetes),

- 10 -

each of which simulated situations indicates a need to induce labour.

To determine the method of induction the maternal abdomen should be palpated noting presentation of the foetus (whether the head or buttocks is in the pelvis), and whether the head is engaged or unengaged in the pelvis (when the maximum diameter of the head is in the pelvic brim — indicated at 29). This is determined by the number of fifths of the foetal head that are palpable through the maternal abdomen. If two fifths or less are thus palpable, it means that the head is engaged which therefore favours a more successful vaginal delivery.

The student should perform a vaginal examination to assess if the cervix is favourable for induction. The following features may be assessed and quantified using the modified score by Bishop: -

SCORE:	0	1	2	3
Dilation of the cervix (cm)	0	1 or 2	3 or 4	5 or more
Consistency of the cervix	Firm	Medium	Soft	
Length of the cervical canal (cm)	> 2	2 - 1	1 - 0.5	< 0.5
Position of the cervix	Posterior	Central	Anterior	
Station of the presenting part of the foetus (cm above the maternal ischial spines)	3	2	1 or 0	Below

If the Total score is in the range 0 – 5 it signifies an unfavourable ('unripe') situation.

If the Total score is in the range 6 – 13 it signifies a favourable ('ripe') situation. (If the cervix is unfavourable, the chance of a good response to labour induction is low).

#### **V. METHOD OF INDUCTION**

This is diagnosed by the student determining the condition of the cervix-simulating opening of the training aid 10.

If the cervix is 'unripe', the student should advise and/or action:

CTG monitoring of the foetal heart rate.

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Placement of a prostaglandin intravaginal pessary or gel. (Prostaglandins stimulate uterine contractions).

Reassessment of the cervix according to the Bishop's score 4-6 hours later and, at that time,

5            Insertion of another prostaglandin gel if the cervix is still not favourable.

Once the cervix is 'ripe', the student should advise and/or action continued CTG monitoring of the foetal heart rate and artificial rupture of membranes using an amnihook.

10          The scenario set by the examiner for training aid 10 can then simulate spontaneous uterine contractions. Alternatively, if uterine contractions are not simulated, the student should decide to augment labour by setting up an intravenous oxytocin infusion. (Oxytocin is a drug that stimulates uterine contractions).

15          Once the simulated uterine contractions are in effect, the student can perform a normal vaginal delivery.

Training aid 10 can respond appropriately to the various methods of induction, the particular response being controlled by the trainer /supervisor or examiner sitting at  
20          the (optionally remote) computer terminal.

## **VI. AUGMENTED LABOUR**

The computer-programmed scenario may simulate varying rates of cervical dilation. During normal labour the cervix generally dilates at a rate of approximately one  
25          centimeter per hour. The drug oxytocin is use to enhance uterine contractions if the cervix is dilating at a slower rate. It is given by intravenous infusion. It should be used cautiously in women who have had more than one pregnancy as it may lead to over stimulation and rupture of the uterus. The student's knowledge of such matters can be readily tested.

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### **VII. OBSTRUCTED LABOUR**

This term relates to circumstances where there is no progress during labour despite strong maternal contractions. It may be due to failure of the cervix to dilate or failure of the presenting part to descend through the birth canal. The student can be informed by the trainer or examiner that the mother (simulated by housing 12 of the training aid 10) is tired, anxious, loses her ability to co-operate, and/or that she is unable to relax and her anxiety increases between contractions. The training aid 10 can then be used to simulate one or more of the following:

Rise in maternal pulse rate and temperature

Early rupture of membranes

Urine output decreases, ketones can be detected on urine dipstick and smelt on mother's breath.

Slow rate of cervix dilation

Foetal distress (intimated for example by display of a slowing of foetal heart rate on the CTG apparatus 27 and/or by the simulated amniotic fluid (pumped into simulated uterine cavity 14) being Meconium stained.

### **VIII. EPISIOTOMY**

This is an incision in the maternal perineum that enlarges the opening to the vagina.

It is used to aid delivery when the perineum is obstructing progress or more room is required for instrumental delivery, assisted breech delivery, or shoulder dystocia. As indicated above, the training aid 10 is provided with a removable area of simulated perineum so that the student can practise making and repairing episiotomies.

### **IX. ASSISTED DELIVERY**

This is the use of forceps or a vacuum extractor (Ventouse) for assisting delivery in the 2<sup>nd</sup> stage of labour. There are 3 types of forceps: short-curved (Wrigley's), long-curved, and Kjelland's, and the student will be required to know which forceps are to be used in used and in which particular situation.

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Indications for the use of forceps are: -

- Delay in the second stage due to or associated with:
  - inadequate uterine contractions and poor voluntary effort
  - resistant pelvic floor and perineum (managed with an episiotomy)
  - 5       - large foetus
  - deep transverse arrest of the head (the foetal head is in such a position that is not compatible with vaginal delivery unless the head is rotated with forceps)
  - other malpresentations, e.g. face or brow presentation;
- 10   — Maternal distress due to or associated with a rise in the maternal pulse rate and temperature and/or an inability to concentrate or co-operate due to a long first stage;
- Foetal distress, measured using CTG, and due to or associated with:
  - . umbilical cord prolapse, tight loop or tie in the cord
  - 15       . placental underperfusion due to hypertension, antepartum haemorrhage, or postmaturity
  - . prolonged or difficult labour;
- Prevention of extra maternal effort, eg severe maternal hypertension;  
Some cases of pre-term delivery as a small head is susceptible to injury during  
20       passage through vagina;
- Delivery for the after-coming head of breech presentation.

In order that the student can practise delivery with forceps, the training aid 10 can simulate the above indications and can accentuate the following conditions that are  
25       required if forceps are to be applied safely and successfully:

- the cervix should be fully dilated
- the presentation must be suitable and must be known
- the head must be engaged (no head palpable above the pelvic brim 29)
- the head must be below the maternal ischial spines
- 30   - membranes should be fully ruptured

- 14 -

- the bladder should be emptied – a catheter should be passed in the bladder to empty it.
- The uterus should be contracting – may be stimulated by intravenous oxytocin infusion

5

The student should be able to assess these simulated parameters successfully on the training aid before he/she can proceed with forceps delivery.

10

Indications for use of a Vacuum extractor (Ventouse) are similar to that of forceps except:

- Maternal effort is required, therefore cannot be used if maternal effort is to be avoided, eg because of severe maternal hypertension,
- It cannot be applied to breech or face presentations,
- Probably less safe in pre-term babies as there is a greater risk of intracranial haemorrhage,
- Only to be performed in three contractions for no more than 20 mins.

15

#### **X. BREECH PRESENTATION**

20

This arises where the presenting part of the foetus is the buttocks. There are different types of breech:

- Extended knee breech (frank breech): the legs are flexed at the hip and extended at the knee.
- Flexed knee breech (complete): the legs are flexed at the hip and the knee
- Footling breech : one or both feet are below the buttocks

25

The model foetus 15 of the training aid 10 can be placed within the simulated uterine cavity 14 in any one of these positions.

30

The student may use training aid 10 to perform external cephalic version in which the foetal presentation is changed by manual pressure through the women's abdominal wall simulation provided by the wall of chamber 12. (This is normally performed in real life

- 15 -

between 36 and 37 weeks gestation). Before effecting external cephalic version, the student/trainee must determine the exact position of the simulated foetal body 15 by palpation, and must establish foetal heart sounds - with hand-held Doppler machine. The technique adopted is as follows:

- 5       – Disengage breech from the pelvis (breech pushed upwards with fingers of both hands);
- The breech is then pressed upwards and laterally with one hand, while the other hand presses on the head in the direction which will increase flexion;
- The simulated foetus 15 is gently turned as if it were doing a forward somersault
- 10      The student should check the foetal heart sound afterwards.

## **XI. VAGINAL BREECH DELIVERY**

### **1<sup>st</sup> stage of labour**

- 15      This corresponds to normal vertex delivery. Once there has been rupture of the membranes, the student should perform a vaginal examination to exclude a cord prolapse (which may be simulated by training aid 10). The student has to keep a watch for failure to progress and/or any maternal or foetal distress, and each of these complications can be simulated on training aid 10.

### **2<sup>nd</sup> stage of labour**

- 20      The student should manoeuvre training aid 10 to simulate the lithotomy position, i.e. both maternal legs placed in stirrups, and perform an episiotomy simulation for easy delivery of the breech and head. In a flexed breech the baby's feet and legs should be eased out on their presentation. As soon as the anterior scapula of the baby is visible
- 25      the anterior arm can be pulled out, and the posterior arm can be freed prior to delivery of the head with or without forceps.

### **3<sup>rd</sup> stage of labour**

- 30      This corresponds to that of normal vertex delivery. This is when the umbilical cord prolapses in to the vagina and possibly through the vaginal opening (the membranes



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may be intact), and generally occurs with a malpresentation although it can also occur with cephalic presentation.

#### **XV. GESTATIONAL DIABETES**

- 5 This refers to diabetes that appears in pregnancy and disappears after delivery. The trainer or examiner indicates to the student that the mother complains of one or more of:
- polydipsia (feeling thirsty) and/or
  - polyuria (increased urinary frequency) and/or
  - 10 - she may have a previous history of previous macrosomic baby (large baby > 4000 g) or unexplained stillbirth, or previous gestational diabetes,
- and the student, using so far as possible training aid 10, performs an examination of the 'patient' for maternal obesity (>20% of ideal birth weight) and signs of polyhydramnios. The student should also advise and/or action performance of a urine
- 15 dipstick test to check for excess glucose and/or ketones, and of blood tests to check for fasting blood glucose of  $\geq 7.9$  mmol/l or  $> 11.0$  mmol/l after 75g oral glucose load (meal). The simulated mother may also (notionally) exhibit signs and symptoms of the complications of diabetes such as pre-eclampsia and/or pre-term labour.
- 20 With the training aid simulating labour, the student should advise or action:
- Setting up a continuous intravenous drip of insulin and 5% dextrose.
  - Monitor blood glucose regularly.
  - Alter infusion rate of insulin according to simulated blood glucose results as given by the trainer, supervisor or examiner.
  - 25 - Effect continuous foetal monitoring with CTG apparatus 27.

The student using the training aid 10 can also attend to complications during labour such as Foetal macrosomia leading to obstructed labour (see above) and or shoulder dystocia, and/or such as Intrauterine growth retardation (low foetal birth weight for

30 gestational age).

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In circumstances of diabetes in pregnancy, the mother may already be an established diabetic, but the features during pregnancy and labour are the same as gestational diabetes.

5

### EPILEPSY

Although pregnancy does not trigger epilepsy or cause an exacerbation of pre-existing epilepsy, the training aid 10 may be actuated to simulate an epileptic fit during labour if the anticonvulsant levels are not maintained adequately during labour. The student should respond as if the mother was having an eclamptic fit.

10

The above-described and illustrated training aid 10 may be modified additionally to provide simulations of gynaecological pathology, including *inter alia* Uterine Tumours and the like, and features associated with Vaginal, Cervical, Vulval, and/or Ovarian and tubal pathology. It may be provided with a simulated anus 13 and a simulated bladder 11 which can be subjected to catheterisation to practise obtaining urine samples to be tested for protein and glucose.

15

Alternatively or additionally, the above-described and illustrated training aid may be modified to provide simulations of various pathology and diseases in the abdomen, breast, head and neck.

20

For example, the simulations associated with the abdomen can simulate *inter alia* one or more of the following conditions:

25

Ascites (fluid in the peritoneal cavity)

Hepatomegaly (enlarged liver)

Splenomegaly (enlarged spleen)

Polycystic Kidneys

Unilateral enlarged kidneys

30

Hernias (Inguinal-Direct and indirect, femoral, incisional, umbilical)

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- Obstructed colon
- Aneurysm (enlarged aorta)
- Superficial venous dilatation
- Lymphadenopathy
- 5 Enlarged lymph nodes
- Bladder pathology

10 For example, the simulations associated with the breast can simulate *inter alia* a variety of breast masses (e.g tumours, cysts, and the like), Lymphadenopathy (Enlarged lymph nodes), and/or Tethering of lumps and skin changes.

15 For example, the simulations associated with the head & neck can simulate *inter alia* a variety of lumps in the head and neck such as Enlarged thyroid, Lumps or nodules in the thyroid, Enlarged lymph nodes, and/or other lumps in the posterior or anterior triangles in the neck.

Modifications of the training aid 10 may also be constructed to to show various pelvic and genito-urinary pathology.

20 Some or all of the above-mentioned lumps and swellings can be simulated by the use of fluid or air filled containers (bags, sacs or the like) having a flexible wall, e.g. formed of latex/plastic/silicone or other suitable material, placed in appropriate locations and arranged such as to be filled/emptied by electrically operated valve means that are operable by the trainer, supervisor or examiner of the student.

25 In preferred use of the above-mentioned embodiments and modifications of the obstetrics training aid, the trainer, supervisor or examiner of the student sits before the central computer terminal 26 and uses it to control the whole body simulator. He/she, or (if appropriate) the student, can make a selection from a host of patient case  
30 histories and the computer will then simulate the appropriate physical signs on the

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maternal body simulated by housing 12 and/or on the simulated foetal body 15. Where provided with the appropriate simulations, the training aid 10 (with or without one or more of the modifications described above) can also be used by a student to practice various gynaecological, obstetric, and other general surgical techniques (both open and laproscopic techniques). For this the control means 25 and computer 26 can be connected to a TV monitor and the computer program can simulate various pathology that is then displayed on screen. Laproscopic surgical techniques can be practised with the laproscope introduced into the training aid 10.

Other modifications and embodiments of the invention, which will be readily apparent to those skilled in this art, are to be deemed within the ambit and scope of the invention, and the particular embodiment(s) hereinbefore described may be varied in construction and detail, e.g. interchanging (where appropriate or desired) different features of each, without departing from the scope of the patent monopoly hereby sought.

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### CLAIMS

1. An obstetrics training aid (10) characterised by:  
a housing (12),  
5 a flexible chamber (14) within the housing (12) to simulate a uterus,  
a foetus-simulating body (15) within the flexible chamber (14),  
the housing (12) having an opening (18) provided with a flexible boundary to simulate  
a cervix, and motion imparting means (20) for moving the foetus-simulating body (15)  
within the chamber (14) in a direction outwardly of the cervix-simulating opening (18)  
10 to simulate a birthing process, i.e. egress of a real foetus from the cervix.
2. An obstetrics training aid according to Claim 1, wherein the motion imparting  
means (20) comprise tubular elements (20) engaging the flexible chamber (14), and  
fluid supply means for introducing fluid under pressure into said tubular elements (20).  
15
3. An obstetrics training aid according to Claim 1 or Claim 2, and further  
comprising:  
electromagnets (22) within the housing;  
elements (24) susceptible to magnetisation attached to the foetus-simulating  
20 body (15) to be magnetically coupled to the electromagnets; and  
control means (25) operable on the electromagnets (22) to effect, via said  
elements (24) susceptible to magnetisation, variations in position of the foetus-  
simulating body (15) within the flexible chamber (14) and/or the housing (12).
- 25 4. An obstetrics training aid according to any preceding Claim, wherein the  
cervix-simulating opening (18) is covered by a removable replaceable membrane (19)  
in simulation of a perineum.
5. An obstetrics training aid according to any preceding Claim, wherein the  
30 flexible chamber (14) contains a liquid to simulate amniotic fluid.

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6. An obstetrics training aid according to Claim 5, wherein the liquid is dyed with a selected one of a plurality of coloured dyes.
- 5 7. An obstetrics training aid according to Claim 6, wherein the said dyes are to simulate blood — as can arise in post-partum haemorrhage — and/or to simulate bowel contents — as can arise in foetal distress.
- 10 8. An obstetrics training aid according to any preceding Claim, wherein the flexible chamber (14) contains a bag (23) attached to said body (15) and simulating a placenta.
- 15 9. An obstetrics training aid according to any preceding Claim, wherein the foetus-simulating body (15) is hollow — at least within a head-simulating portion (16) thereof — and said portion (16) contains fluid.
- 20 10. An obstetrics training aid according to any preceding Claim, wherein the housing (12) and chamber (14) are operable to permit removal of the foetus-simulating body (15) and its replacement by another such body (15) of different size and/or weight.
- 25 11. An obstetrics training method characterised in that an obstetrics training aid (10) according to any preceding Claim is utilised, and wherein said motion imparting means (20) is operated to move said foetus-simulating body (15) within said chamber (14) in a direction outwardly of said cervix-simulating opening (18) to simulate a birthing process, i.e. egress of a real foetus from the cervix.
- 30 12. An obstetrics training method characterised in that an obstetrics training aid (10) according to Claim 2, or to any one of Claims 3 to 10 when dependent therefrom, is utilised and wherein the tubular elements (20) are filled sequentially with water or air under pressure to effect a squeezing action on the foetus-simulating body (15),

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and, due to the latter's curved shape, effect movement of the foetus- simulating body (15) in a direction outwardly of the cervix-simulating opening (18).

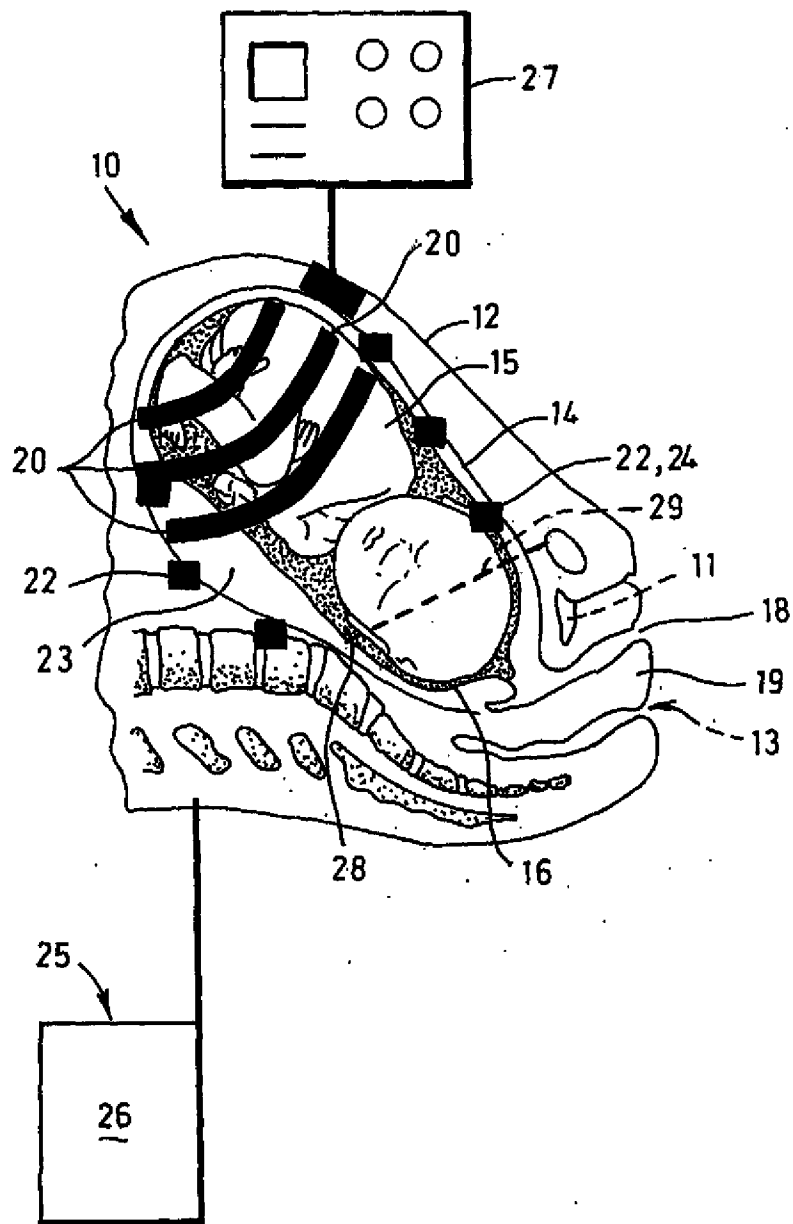
5 13. An obstetrics training method according to Claim 12, characterised in that the fluid supply to the tubular elements (20) is varied cyclically, e.g. via a foot-operated pump, to simulate maternal contractions.

10 14. An obstetrics training method according to any one of Claims 11 to 13, characterised in that an obstetrics training aid according to Claim 3, or to any one of Claims 4 to 10 when dependent therefrom, is utilised and in that said control means (25) is operated to simulate one or more of a variety of positions and/or presentations of said foetus-simulating body (15).

15 15. An obstetrics training method according to any one of Claims 11 to 14, characterised in that an obstetrics training aid according to Claim 4, or to any one of Claims 5 to 10 when dependent therefrom, is utilised and wherein an episiotomy procedure is practised on said removable replaceable membrane (19).

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## INTERNATIONAL SEARCH REPORT

National Application No

PCT/GB 01/02492

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 G09B23/28

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G09B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 826 019 A (KNAPP C ET AL)	1,8-11
A	30 July 1974 (1974-07-30) the whole document	2,12-14



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents:

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\*O\* document referring to an oral disclosure, use, exhibition or other means

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\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*&amp;\* document member of the same patent family

Date of the actual completion of the international search

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 01/02492

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 3826019	A	30-07-1974	US 3797130 A	19-03-1974
			US 3824709 A	23-07-1974
			US 3822486 A	09-07-1974
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